9-0900-5339-1

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS

FOR THE MINNESOTA DEPARTMENT OF HEALTH

In the Matter of the Proposed Adoption of Rules of the Minnesota Department of Health Governing Sources of Ionizing Radiation, Minn. Rules Chapter 4730.

REPORT_OF_THE ADMINISTRATIVE_LAW_JUDGE

The above-entitled matter came on for hearing before Administrative Law Judge Phyllis A. Reha on April 26, 1991, at 9:00 a.m. in the Chelsey Room of the Minnesota Department of Health, 717 Delaware Street Southeast, Minneapolis, Minnesota.

This Report is part of a rulemaking proceeding held pursuant to Minn. Stat. ÞÞ 14.131 to 14.20, to hear public comment, to determine whether the Minnesota Department of Health (MDOH or Department) has fulfilled all relevant substantive and procedural requirements of law applicable to the adoption of the rules, whether the proposed rules are needed and reasonable and whether or not modifications to the rules proposed by the MDOH after initial publication are impermissible substantial changes.

Paul Zerby, Special Assistant Attorney General, 525 Park Street, St. Paul, Minnesota 55155, appeared on behalf of the MDOH. The MDOH's hearing panel consisted of Jane A. Nelson, Rule Coordinator of the Environmental Health Division of the MDOH; William Breitenstein, Radiation Specialist and Unit Leader of the X-ray Unit of the Radiation Control Section of MDOH; June Hart, Radiation Specialist of the X-ray Unit of the MDOH; Susan McClanahan, Radiation Specialist of the X-ray Unit ; and Judith Ball, Principal Policy Analyst of the Environmental Health Division of the MDOH.

Forty-one persons attended the hearing. Thirty-eight persons signed the hearing register. The hearing continued until all interested persons, groups or associations had an opportunity to be heard concerning the adoption of these rules.

The record remained open for the submission of written comments for twenty calendar days following the date of the last hearing, to May 16, 1991. Pursuant to Minn. Stat. Þ 14.15, subd. 1 (1988), three business days were

allowed for the filing of responsive comments. At the close of business on May 21, 1991, the rulemaking record closed for all purposes. The Administrative Law Judge received written comments from interested persons during the comment period. The MDOH submitted written comments responding to matters discussed at the hearings and making changes in the proposed rules.

The MDOH must wait at least five working days before the agency takes any final action on the rule(s); during that period, this Report must be made available to all interested persons upon request.

Pursuant to the provisions of Minn. Stat. Þ 14.15, subd. 3 and 4, this Report has been submitted to the Chief Administrative Law Judge for his approval. If the Chief Administrative Law Judge approves the adverse findings of this Report, he will advise the MDOH of actions which will correct the defects and the MDOH may not adopt the rule until the Chief Administrative Law Judge determines that the defects have been corrected. However, in those instances where the Chief Administrative Law Judge identifies defects which relate to the issues of need or reasonableness, the MDOH may either adopt the Chief Administrative Law Judge's suggested actions to cure the defects or, in the alternative, if the MDOH does not elect to adopt the suggested actions, it must submit the proposed rule to the Legislative Commission to Review Administrative Rules for the Commission's advice and comment.

If the MDOH elects to adopt the suggested actions of the Chief Administrative Law Judge and makes no other changes and the Chief Administrative Law Judge determines that the defects have been corrected, then the MDOH may proceed to adopt the rule and submit it to t

When the MDOH files the rule with the Secretary of State, it shall give notice on the day of filing to all persons who requested that they be informed of the filing.

Based upon all the testimony, exhibits, and written comments, the Administrative Law Judge makes the following:

FINDINGS OF FACT

Procedural_Requirements

1. On February 19, 1991, the MDOH filed the following documents with the Chief Administrative Law Judge:

(a) A copy of the proposed rules not certified by the Revisor of Statutes;
(b) A copy of the MDOH's Authorizing Resolution;
(c) A copy of the MDOH's proposed Order for Hearing;
(d) The Notice of Hearing proposed to be issued; and,

(e) The Statement of Need and Reasonableness (SONAR).

On February 27, 1991, the MDOH filed a copy of the proposed rules certified by the Revisor of Statutes.

2. On March 6, 1991, the MDOH mailed the Notice of Hearing to all persons and associations who had registered their names with the Board for the purpose of receiving such notice and all persons to whom the Agency gave discretionary notice.

3. On March 11, 1991, a copy of the proposed rules and the Notice of Hearing were published at 15 State Register 1946.

4. On April 1, 1991, the MDOH filed the following documents with the Administrative Law Judge:

(a) The Notice of Hearing as mailed;
(b) a copy of the State Register containing the Notice of Hearing and the proposed rules;
(c) a copy of the Notice of Solicitation of Outside Opinion together with all materials received in response to that notice.
(d) The Agency's certification that its mailing list was accurate and complete and the Affidavit of Mailing the Notice to all persons on the MDOH's mailing list;
(e) a fiscal note;
(f) a copy of the letters requesting a rule hearing, and,
(g) The executed Order for Hearing.

5. The MDOH rules as published contained an error in which the wrong symbol was used in eight places in the published rules. The MDOH published an errata sheet containing the correct symbol which appeared at 15 State Register 2439 on April 29, 1991. The record contains no evidence that any person was adversely affected by the error in the State Register. The error in the published rules and the publication of an errata sheet do not constitute substantial procedural defects which would require republication of the rules or a new rulemaking proceeding.

Statutory_Authority.

6. In its SONAR, the MDOH cites Minn. Stat. ÞÞ 144.05(c); 144.12, subd. 1(15); and 144.121, subd. 2 as the Department's statutory authority to promulgate the proposed rules. Minn. Stat. Þ 144.05(c) is the statement of general authority granted to the Commissioner of MDOH to set and enforce health standards and regulate health facilities to protect the public. Under Minn. Stat. Þ 144.12, subd. 1(15), the Commissioner is authorized to promulgate reasonable rules to protect the public health and control "the handling, storage, transportation, use and disposal of radioactive isotopes and fissionable materials." Periodic inspections of the sources of ionizing

radiation are required under Minn. Stat. Þ 144.121, subd. 2, which states:

> Periodic radiation safety inspections of the sources of ionizing radiation shall be made by the state commissioner of health. The frequency of safety inspections shall be prescribed by the commissioner on the basis of the frequency of use of the source of ionizing radiation; provided that each source shall be inspected at least once every four years.

Based on the three statutory provisions cited above, the Administrative Law Judge concludes that the MDOH has the statutory authority to promulgate rules governing ionizing radiation.

Nature_of_the_Proposed_Rules.

6. In the course of providing medical, dental, and veterinary treatment carries the risk of harm, either through exceptionally large doses of radiation or through disease triggered by radiation. As a result of those risks, restrictions have been adopted at both the federal and state level for the use of radiation in medicine and limits have been placed on how much radiation workers can be exposed to in the workplace. 29 C.F.R. Þ 1910.96.

The existing rules governing ionizing radiation were adopted in 1971. Technical changes to those rules were made in 1978, 1986, 1988, and 1990. The MDOH believes that the rules governing the use of X-ray technology must be updated to conform with the innovations in X-ray technology to protect public health. SONAR, at 2. To ensure that the proposed rules have a good "fit" with the current applications of X-rays, the MDOH assembled an Advisory Work Group (AWG) composed of professionals from a variety of fields whose common interest is the use of ionizing radiation. The members of the AWG are identified in the MDOH SONAR, Exhibit A. Among the groups represented are the American Association of Physicists in Medicine, the Minnesota Chiropractic Association (MCA), the Minnesota Dental Association (MDA), Minnesota Dental Hygienists, the Minnesota Hospital Association (MHA), the Minnesota Medical Association (MMA), the Minnesota Podiatric Medical Association, the Minnesota Radiological Society, the Minnesota Society of Radiologic Technologists, the Minnesota Veterinary Medicine Association, and the North Central Chapter of the Health Physics Society. The AWG provided advice to the MDOH on specific provisions of the proposed rules.

The efforts of the MDOH and the AWG resulted in proposed rules which set performance standards, set requirements for protective shielding, establish quality assurance (QA) requirements, and require reporting to verify the safe operation of radiologic equipment. The MDOH stated the purpose of the proposed rules is to "enable users to keep x-ray doses as low as reasonably achievable

for diagnostic x-rays and enable therapeutic x-ray doses to be precise and accurate to avoid over exposure." SONAR, at 3. The specific standards chosen are based on publications by the Conference of Radiation Control Program Directors, the National Council on Radiation Protection and Measurements, and the American Association of Physicists in Medicine. SONAR, at 4. The "finished product" of the rule development process are the rules as proposed in this rulemaking. These proposed rules consist of 148 pages of new and revised material.

Small_Business_Considerations_in_Rulemaking.

7. Minn. Stat. Þ 14.115, subd. 2, provides that state agencies proposing rules affecting small businesses must consider methods for reducing adverse impact on those businesses. The MDOH examined each method suggested by that statute to reduce the impact of the proposed rules on such businesses. SONAR, at 6-7. The MDOH concluded that simplifying performance standards, easing reporting reuqirements, or exempting small businesses from any of the proposed rules are not consistent with protecting public health. The MDOH has considered methods for reducing the impact of these rules on small business and thus has complied with Minn. Stat. Þ 14.115, subd. 2.

Fiscal_Notice.

8. Minn. Stat. Þ 14.11, subd. 1, requires the preparation of a fiscal notice when the adoption of a rule will result in the expenditure of public funds in excess of $100,000 per year by local public bodies. The notice must include an estimate of the total cost to local public bodies for a two-year period. The MDOH estimates the proposed rules will require yearly expenditures by local governmental units of $148,441 for each year of the two years following the adoption of these rules. In addition, the MDOH expects to spend $229,086 to implement the rules over those two years needed. Other state agencies are expected to incur additional costs of $154,412 per year complying with these rules. As required by Minn. Stat.

Impact_on_Agricultural_Land.

9. Minn. Stat. Þ 14.11, subd. 2 (1988), imposes additional statutory requirements when rules are proposed that have a "direct and substantial adverse impact on agricultural land in this state." The statutory requirements referred to are found in Minn. Stat. ÞÞ 17.80 to 17.84. The proposed rules will have no substantial adverse impact on agricultural land within the meaning of Minn. Stat. Þ 14.11, subd. 2 (1988).

Analysis_of_the_Proposed_Rules.

10. The rules proposed in this proceeding are almost exclusively technical in nature. As discussed at Finding 6, above, the MDOH has drafted the proposed rules with the assistance of the AWG, whose members are professionals in the use of ionizing radiation. The result of the drafting process is an extraordinarily complicated set of rules supported by a detailed Statement of Need and Reasonableness which is 155 pages in length. The care with which the proposed rules were drafted is reflected in the relatively few critical comments received through this rulemaking proceeding. Due to the scope and nature of the rules, the Administrative Law Judge will not comment on any rule part which did not receive critical comment or otherwise needs discussion. Any rule not discussed in this Report is found to be needed and reasonable. In locations where a change is made affecting more than one rule part, only the first instance of that change will be discussed. Any change in the rules proposed by the MDOH not specifically mentioned in this Report is found not to constitiute a substantial change.

Proposed_Rule_4370.0100_-_Definitions.

11. Proposed rule part 7005.0705, as modified by the MDOH after the hearing in this matter, is composed of over two hundred subparts, each defining a term used in the proposed rules. As discussed at Finding 10, above, only those items which received comment or require analysis will be expressly referred to in this Report. All other definitions not expressly referred to in this Report are found to be needed and reasonable.

12. Subpart 2 defines "absorbed dose" for the purpose of measuring exposure to ionizing radiation. Terrance N. Teslow, Ph.D., suggested that the definition was confusing since it used both "a known volume and mass" to describe one element of the defined term. Dr. Teslow suggested that "a known mass" would be a better definition since volume is not actually a factor in absorbing radiation. The MDOH agreed with this comment and changed the definition accordingly. The subpart, as modified, is needed and reasonable and the change does not constitute a substantial change.

13. The definition of "applicator" is set out at subpart 8. Thomas Hench, health physicist with the Department of Veteran's Affairs (DVA), suggested that the definition in this subpart actually describes a collimator. The MDOH agreed that the definitions are similar, but maintains that the distinction between these two devices must be maintained for the device used in radiation therapy. MDOH Responses to Comment, at 2. The proposed definition of "applicator" is needed and reasonable.

14. Subpart 9, defining "appropriate limit," changes an existing rule definition only to the extent that it deletes several references. The DVA suggested that the better term would be "maximum appropriate limit" since lower

dosages are allowed under the rule. The MDOH responded that the use of the word "may" in the rule allows any amount up to the doses specified, and thus already incorporates the suggestion of the DVA. There has been no suggestion that the subpart is vague or confusing. Subpart 9 is needed and reasonable.

15. Dr. Teslow suggested that "foil" be added to subpart 20, defining "beam scattering filter," on the ground that "foil" is another name for the filter used to scatter beams of electrons. The MDOH agreed with Dr. Teslow's suggestion and added "foil" to the definition. Subpart 20, as modified, is needed and reaso

16. Subpart 24, item B defines "by-product material" in terms of tailings
and waste produced by thorium or uranium extraction or concentration from ore.
The DVA suggested deletion of this item on the ground that the rules were only
applicable to medical applications. The MDOH responded that the rules apply to
industrial uses of radiation as well as medical uses and the U.S. Nuclear Regulatory Commission uses the same definition. Subpart 24 is needed and reasonable as proposed.

17. The DVA and Dr. Teslow suggested changes to the definition of "calibration" set out in subpart 26. The MDOH responsed to the suggestions by
deleting the units of calibration language after the three items of the subpart. The deletion removes two different methods of measurement which, on their face, do not appear consistent. Subpart 26, as modified, is needed and reasonable. The modification reduces the likelihood of confusion and does not
constitute a substantial change.

18. The DVA suggested that the definitions in subpart 35 ("coefficient of
variation or C") and subpart 36 ("cold flow") are unnecessary. The MDOH responded to the suggestion by noting that the terms are not commonly used yet
appear in the proposed rule. The definitions are needed and reasonable to define terms which, because of their lack of a commonly accepted meaning, could
cause an incorrect interpretation of the proposed rules.

19. "Contact therapy system," as originally proposed in subpart 42, included both systems which touched the surface being treated and those systems
for which the x-ray tube port comes within five centimeters of the surface. Dr. Teslow suggested that electron beam applicators would fall
within this definition, but are not contact therapy systems. The MDOH acknowledged that the comment was correct, and deleted the "within five centimeters" portion of subpart 42. The subpart, as modified, is needed and reasonable. The change conforms the definition to the systems intended and does not constitute a substantial change.

20. The DVA objected to the definition of "control panel" (located in subpart 43), on the ground that it required the switches, knobs, and other

hardware to operate an x-ray system to be located behind a protective barrier.
The commentator pointed out that many systems do not put their control panels behind barriers. The MDOH acknowledged the validity of the comment and deleted
the location language from the definition. As modified, subpart 43 is needed and reasonable. The change removes unreasonable language and does not constitute a substantial change.

21. "Coulumb per kilogram (C/kg)" is defined as the unit of exposure and
the definition includes the formula for converting from C/kg to the roentgen (another unit of radiation measurement) in subpart 45. The DVA suggested changing the definition to expressly define the roentgen. The MDOH declined to
make that change. The clear purpose of the definition is to provide a standard
cross-reference from one system of measurement to another. The definition is needed and reasonable as originally proposed.

22. The "CT dose index (CTDI)" is defined in subpart 47 by a graphic formula. Dr. Teslow suggested that the definition would be clarified by changing the last part of the last sentence to "the increment of adjacent scans
is nT." The MDOH recognized that the existing language was awkward and adopted
the commentator's suggestion. Subpart 47, as modified, is needed and reasonable. The change is not a substantial change.

23. Subpart 52 defines "densitometer" as "an instrument that measures the
density of a film by measuring the amount of light transmitted through the film." Dr. Teslow suggested that the definition would clarify the meaning of "density" as used in this subpart if the word "optical" was added. This would
differentiate between measuring opacity, which is the intended use, and measuring the ratio of weight to volume, which is the common usag

24. "Exposure" is defined in subpart 68. Dr. Edwin C. McCullough of the
Mayo Clinic suggested that the definition would be clarified by adding a reference to the roentgen as being the unit of exposure. The MDOH agreed with
this suggestion an added a sentence including that language. The addition makes application of the standards for human exposure contained in these rules
easier to apply. The subpart, as modified, is needed and reasonable. The change does not constitute a substantial change.

25. According to the MDOH, two different measuring systems are used in the ionizing radiation industry. MDOH Response to Comments, at 5-6. The gray
(Gy) is a unit in one measurement system and it is defined by the number of joules/kilogram. In addition, the definition also references the other measurement system in subpart 79, by setting out the equivalent Gys to one rad.

DVA suggested that the reference to rads be deleted. Dr. McCullough suggested instead that the reference be changed to base the formula on the gray, not the rad. The MDOH adopted the latter suggestion and altered the formula to reflect the number of rads to the gray. The end result of this modification resolves both commentators' concerns. The definition of gray is needed and reasonable to set performance standards. The reference to the rad system of measurement is needed and reasonable to compare the two measuring systems. The modification improves the readability of the rule and does not constitute a substantial change.

26. Subpart 104 defines "light field" as meaning "the area the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection." Dorothy Rathe and DVA criticised this subpart as being difficult to read and comprehend. The MDOH acknowledged those comments, but declined to change the subpart on the ground that the subpart expresses federal performance standards and the Department could not devise simpler language which captures the concept. The Administrative Law Judge finds the subpart to be needed and reasonable. The subpart is not too difficult to understand, if the reader is patient and uses conceptual aids. Nevertheless, the MDOH is encouraged to look at this subpart again, with the idea of making it easier to understand. In the alternative, the Department may wish to prepare a graphic, identifying each aspect of the definition of "light field" and use the graphic as an interpretive tool. Such a graphic is not required to be adopted as a rule and need not be submitted to the Revisor.

27. Subpart 111 defines "maximum permissible concentrations (MPC)." Robert G. Wissink, Manager of Health Physics Services for the Minnesota Mining and Manufacturing Company, objected to the inclusion of this term in the proposed rules as being obsolete. He suggested that the term be replaced by "annual limit of intake (ALI)" and "derived air concentration (DAC)" which are the terms now used in place of MPC. The Department responded that the new terms are found in unpromulgated rules of the Nuclear Regulatory Commission. At present, the term used in the existing federal regulations is MPC. The Department stated in its response that it can amend these rules once the federal terminology is finally adopted. The use of MPC is needed and reasonable to ensure consistency between the federal and Minnesota standards.

28. "Nominal treatment distance" is defined in subpart 119. As originally published, the definition was divided into two parts for electron irradiation and x-ray irradiation. Dr. McCullough suggested that the definition was cumbersome and suggested the term be defined by field size. Additionally, Dr. McCullough's suggested language clarifying that, for isocentric systems, the nominal treatment distance is ordinarily the source-to-axis distanc

29. Subpart 121, as originally proposed, defined "optical density or O.D." as "the logarithm of the reciprocal of the transmitted light." Dr.

Teslow suggested that the definition be changed to "the logarithm of the incident light intensity minus the logarithm of the transmitted light intensity." The MDOH accepts the suggested language because it clarifies the original definition. The new language is needed and reasonable to define "optical density." The modification to the subpart better expresses the Department's intent and does not constitute a substantial change.

30. Dr. McCullough suggested that subpart 131, defining "port film," be changed to reflect the latest equipment used in the field. To that end, he suggested adding "portal imaging" to the definition. The MDOH agreed with the comment and added "portal imaging" as another term defined in this subpart. The new term was defined by adding "electronic image" to the body of the subpart. The new language incorporates new technology into the rule and is needed and reasonable. The modification to this subpart as published does not constitute a substantial change.

31. "Therapeutic field size" is defined in subpart 196. Dr. McCullough suggested that the definition be clarified by reorganizing one sentence of the proposed definition into two sentences and using more readily understood language. The MDOH agreed with the comment by dividing the definition into two sentences and by stressing that the field size is defined by the 50 percent distance from the central axes. The subpart is needed and reasonable to clearly state the intended definition. The modification clarifies the rule and does not constitute a substantial change.

32. Dr. Teslow urged the adoption of a definition of "kinetic energy released in matter (KERMA)," as a measure of radiation in air, since brachytherapy radiation sources are to be calibrated by that measure. The MDOH declined to add that definition to this part because KERMA does not appear in the proposed rules. In its Response to Comments, the Department states that if the federal standards adopt the term and the MDOH believes defining that term becomes necessary, it will define the term in future rule revisions.

Proposed_Rule_4730.0310_-_Permissible_Doses,_Levels,_and_Concentrations.

33. Proposed rule part 4730.0310 is composed of all new material and sets the limits of radiation exposure for all registrants' employees. The purpose of the proposed rule is to protect persons whose occupations bring them into close contact with sources of ionizing radiation. The specific levels proposed in this rule part come from the National Council on Radiation Protection and Measurements (NCRP) Report 91. Jerry Staiger, Radiation Safety Officer of the University of Minnesota, and Mr. Wissink questioned whether subpart 2 of proposed rule 4730.0310 could legitimately require, rather than recommend, mandatory adherence to a stricter exposure limit by pregnant women than the exposure limit for all workers. The MDOH responded that the decision to make the levels recommended by NCRP mandatory for pregnant women was based on the need to protect the health of the fetus, since it is particularly susceptible

to the harmful effects of radiation.

The legality of employers placing occupational limitations on pregnant women under Title VII (42 U.S.C. Þ 2000e et seq.) is discussed in a recent United States Supreme Court case, International_Union,_UAW_v._Johnson_Controls, Inc., 111 S.Ct. 1196 (1991). In that case, an employer excluded all fertile women, whether pregnant or not, from working in lead-exposed jobs on the ground that the company was protecting present and future fetuses of employees. The Supreme Court held that the employer's policy of barring all women, except those whose infertility was medically documented was not a bona fide occupational qualification (BFOQ) and thus the policy constituted sex discrimination under the Civil Rights Act of

> Our case law, therefore, makes clear that the safety exception is limited«to instances in which sex or pregnancy actually interferes with«the employee's ability to perform the job. This approach is consistent with the language of the BFOQ provision itself, for it suggests that permissible distinctions based on sex must relate to ability to perform the duties of the job. Johnson Controls suggests, however, that we expand the exception to allow fetal protection policies«that mandate particular standards for pregnant or fertile women. We decline to do so. Such an expansion contradicts not only the«language of the BFOQ and the narrowness of its exception but the plain language and history of the Pregnancy Discrimination Act.

Johnson_Controls, 111 S.Ct. at 1206.

However, Justice Blackmun also recognized that regulatory agencies appropriately consider and develop regulatory standards which require compliance by employers and which establish mandatory protections which minimize risk to the fetus and newborn child:

> It is worth noting that OSHA gave the problem of lead lengthly consideration and concluded that "there is no basis whatsoever for«the«claim that women of childbearing age should be excluded from«the«workplace in order to protect the fetus or the course of pregnancy." 43 Fed.Reg. 52952, 52966 (1978). See also id., at 54354,«54398. Instead, OSHA established a series of mandatory protections which, taken together, "should effectively minimize any risk«to the fetus and newborn child." Id., at 52966. See 29 C.F.R. Þ«1910.125(k)(ii) (1989).

Johnson_Controls, at 1208.

Thus, while it is improper sex or pregnancy discrimination for an employer to bar all fertile or pregnant women from the workplace due to lead [or radiation] exposure, it is appropriate for regulatory agencies to develop reasonable and mandatory standards to minimize risk to the fetus or newborn child, or to any other employee, male or female that is exposed to lead or radiation at the workplace. However, it is still unclear from the holding in

Johnson_Controls whether a regulatory agency can promulgate a different standard for pregnant and fertile women than for men. It is the opinion of the Administrative Law Judge that if the agency has scientific supporting data which establishes the need and reasonableness of a different standard that it would not be an unconstitutional violation of equal protection. See Welsand_v. State_of_Minnesota_Railroad_and_Warehouse_Commission, 88 N.W.2d 834, 838 (Minn. 1958); see also State_by_Spannaus_v._Hopf, 323 N.W.2d 746, 753 (Minn. 1982). The Supreme Court declined to decide whether Title VII preempts state law in a case of this type, because that specific issue was not before it. See Johnson Controls, 111 S.Ct. at 1208-09. However, the Administrative Law Judge does not believe that Johnson_Controls is applicable to this agency rule. The proposed rule does not require or prohibit the use of any particular type of radiation by pregnant women. The rule merely indicates how much exposure is permissible in any given time period. The Administrative Law Judge could find no clear authority which would support a conclusion that the proposed rule, which sets reasonable standards of exposure to ionizing radiation by pregnant women, is unconstitutional or conflicts with substantive law. Absent a clear decision by a reviewing court that such administrative rules do conflict with federal law, the MDOH can adopt the proposed rule. The rule is needed and reasonable to incorporate a recognized standard of protection for pregnant women and fetuses, who are vulnerable to the harmful effects of ionizing radiation.

Mr. Staiger objected to the exposure limits for workers on the ground that a person could reach the exposure limit and then be unable to obtain needed medical x-rays or treatment. The MDOH responded to this comment by exempting n

> According to part 4730.0340, and except as provided in item C, no registrant shall possess, use, receive, or transfer sources of radiation in such a manner as to cause any individual in a restricted area to receive in any period of one calendar quarter from all sources of radiation, excluding natural background radiation sources and radiation from diagnostic or therapeutic x-rays received_by_the_individual_after_the limitations_in_this_item_have_been_reached, a total occupational dose in excess of the standards specified in the following table:
>
> [table omitted]

The suggested language expresses the idea that any diagnostic, therapeutic, or background radiation should count as a part of the total occupational dose, but should not preclude therapeutic or needed medical x-rays once that limit is reached. If the Department intends to have the exemption work in that fashion,

the suggested language clearly expresses that concept. If the MDOH intends that diagnostic, therapeutic, and background exposures not be counted toward the total occupational exposure limit, then the language proposed by the Department more accurately expresses the thought. In either event, the rule is found to be needed and reasonable. Either change in the rule language will clarify the impact of the rule and does not constitute a substantial change.

Proposed_Rule_4730.0340_-_Determination_of_Accumulated_Occupational_Dose.

34. Proposed rule 4730.0340 establishes the methods by which registrants will calculate and track the exposures of their workers. The proposed rule establishes a baseline from information disclosed by the worker of prior exposures. The registrant mus make a reasonable effort to obtain the worker's prior exposure records or claculate the total exposure assuming a calendar quarter, when records are unavailable. The DVA objected to the rule as "overkill" in medical, dental, and veterinary settings. Dorothy Rathe questioned what would be considered "reasonable efforts" to obtain previous work exposure records. The MDOH responded that the rule was intended to prevent overexposure, particularly where the worker changes employers. "Reasonable efforts" is a variable standard which is different in every situation. It is impossible to state exactly what would constitute "reasonable efforts." The Department suggested that a letter and some sort of follow-up would most likely be reasonable. MDOH Response to Comments, at 13. The Judge finds that the methods of determining the occupational exposure of workers in this proposed rule part are needed and reasonable. The "reasonable efforts" standard is not so vague as to constitute a defect. However, the MDOH may want to consider developing some language which would incorporate what constitutes reasonable efforts in most situations. Such language would not constitute a substantial change.

Proposed_Rule_4730.0380_-_Public_Permissible_Levels_of_Radiation_from_External_Sources_in_Unrestricted_Areas.

35. Richard Geise, Certified Radiological Physicist at the University of Minnesota Medical School, suggested that the MDOH modify the proposed exposure limits in unrestricted areas to "grandfather" existing installations. He asserted that the shielding of unrestricted occupied areas should be determined by the length of time persons spend in that area. The Department responded to the comment by deleting the less restrictive standard for persons periodically in an area. The MDOH explained the deletion as needed to protect workers, often nonradiation workers, who are continually in the vicinity of ionizing radiation. The Department described the higher level as inconsistent with the shielding requirements already in place. The Department did not propose to

alter the rule to exempt existing facilities. While this response was not what the commentator intended, the deletion is needed and reasonable to protect persons in unrestricted areas from

Proposed_Rule_4730.1210_-_Prohibited_Uses.

36. Proposed rule 4730.1210 identifies uses of radiation and radiation-producing devices which are prohibited. Only a few prohibitions received comment. George Wilenius, Ph.D., submitted a comment on behalf of Xi Tech, Inc., a manufacturer of hand-held fluoroscopes. This commentator suggested that low-power fluoroscopes be exempted from the prohibition against hand-held devices. The commentator submitted exhibits which indicated that those persons using the device would be exposed, but the exposure could be limited by use of protective clothing and careful positioning of the limb being examined with the fluoroscope. Other commentators also suggested that the low power devices should not be prohibited, since the amount of scatter radiation from such devices is limited. The Department responded that the use of the device is not prohibited, only the practice of operating the device in the hands of the worker is prohibited. The MDOH pointed out that stands are available to mount these devices and the additional distance between the operator and the device is important to keep exposure within acceptable limits.
The materials accompanying the Xi Tech comment indicate that the ordinary use of the fluoroscope is not accompanied by the use of protective clothing and results in significant exposures to radiation by the operator. The prohibition of hand-held devices is needed and reasonable to protect the health and safety of radiation workers.

37. Another prohibited use which received comment was the prohibition in subpart 2, item E against using fluoroscopes to position patients for radiographic imaging. Dr. McCullough suggested that the prohibition might be misinterpreted to prohibit positioning radiation therapy simulators for administering therapeutic doses of radiation. Dr. McCullough stated that the level of radiation in a therapeutic dose is so much higher than the simulator exposure, and the need for correct positioning is so vital, that prohibiting such simulators would be unreasonable. The MDOH agreed with this comment and added language permitting the use of radiation therapy simulators. The rule part, as modified, is needed and reasonable and the additional language does not constitute a substantial change.

38. Heather Benson, Radiology Manager of Children's Hospital of St. Paul, together with many other commentators, suggested that fluoroscopy and C-arm fluoroscopes could be used "under the supervision of a licensed practitioner of the healing arts" rather than by such a practitioner. The MDOH responded to that comment by noting that, while technicians set up and monitor the equipment, the practitioner actually manipulates the device to obtain the

imaging needed for further care. The Department modified subpart 2, item F to reflect that distinction. The item, as modified, prohibits the use of the devices when a practitioner of the healing arts "is not physically present in the room." The change clarifies the item and is needed and reasonable to ensure that exposure to radiation is only performed with a practitioner present. The modification is not a substantial change.

Proposed_Rule_4730.1510_-_Registratant's_Safety_Requirements.

39. This proposed rule requires a number of safety procedures to be followed when operating x-ray equipment. Some commentators questioned the propriety of the procedures set out in subparts 6, 7, 8, and 12 of proposed rule 4730.1510. Subpart 6 allows only the individual receiving therapy to be in the treatment room during exposure. Dr. McCullough recommended that the subpart be changed to allow a present practice of having the tube housing held by a worker when the system is operating at less than 50 kVp (kilowatt peak) and the worker is wearing protective clothing. The Department agreed with the comment and altered the subpart to exclude individuals only when the system is operating at a power above 50 kVp.

Subpart 7 requires le

Mechanical holding devices are the preferred method of providing additional support to patients when that support is needed to obtain adequate imaging. The Department deleted the second sentence in subpart 8 to eliminate a reference to situations which can not be used pursuant to these rules and to clarify that the use of mechanical holding devices must be used when the technique permits.

Mr. Staiger and Mr. Nelson suggested that language be deleted from subpart 12 which suggested that either protective clothing or personnel monitoring devices could be worn when conducting exposures. The Department intended only that placement of the devices relative to the protective clothing be expressed. Rather than risk confusion, the MDOH deleted the reference to monitoring devices. Those commentators also suggested that redundancy and confusion can be reduced in subpart 12, item C by deleting certain language regarding the registrant and personnel monitoring equipment. The Department agreed with these comments and made the suggested changes. All the modifications made to proposed rule 4730.1510 improve the clarity of the rule part and none of them are substantial changes. Proposed rule 4730.1510 is needed and reasonable, as modified.

Proposed_Rule_4730.1520_-_Records_to_be_Maintained_by_the_Registrant.

40. As part of the Department's responsibility to regulate ionizing radiation, the MDOH has proposed that any registrant retain certain records on

each x-ray system used, including the identify of the particular equipment, results of safety surveys, and personnel records. A number of commentators objected to the records identified in proposed rule 4730.1520 as being unreasonable and unnecessary. In subpart 1, the MDOH modified item B to require identifying numbers only of the control console and x-ray tube. This change limits the numbers required to be recorded to the most crucial parts of the x-ray equipment. The Department deleted items C, D and E, relating to the number and frequency of equipment usage, because the information was subject to frequent change and was not important to the MDOH's regulatory responsibilities. Item H, requiring a floor plan of the x-ray equipment location, was also deleted at the suggestion of the Minnesota Dental Association (MDA), as being too costly to justify the minimal benefit derived by the Department. These changes to proposed rule 4730.1530, subpart 1 are not substantial changes; but they do greatly reduce the volume of recordkeeping required of registrants. Subpart 1 is needed and reasonable, as modified.

41. Subpart 2 requires the retention of mammograms for seven years. In its Response to Comments, the Department noted that its concern was for the retention of baseline mammographic images. The MDOH modified subpart 2 by adding "baseline" to clarify its intent. The subpart, as modified, is needed and reasonable and does not constitute a substantial change.

42. Mr. Wissink objected to the language of subpart 4, which requires employers to retain employee monitoring data "indefinitely." The length of that retention requirement is unreasonable. The Department modified the subpart to require retention for the lesser of 20 years or the lifetime of the individual whose records are retained. The modification conforms the employee recordkeeping requirement in subpart 4 to requirements in other parts of the rule. Retaining employee records for the individual's lifetime or 20 years is needed and reasonable to ensure that a person's record of exposure to ionizing radiation is available. The change is not a substantial change.

Proposed_Rule_4730.1530_-_Ordering_of_Radiographic_Examinations.

43. Proposed rule 4730.1530 essentially requires that any examination must have a written request from a healing arts practitioner who is licensed to make determinations on the need for radiographic examinations, with the type of examination specified on the request. Commentators objected to written notation of the request. MDOH Response to Comments, at 23. The chart notation option is consistent with the language recommended by the MDA. Andrea J. Linner, Attorney for the State Farm Mutual Insurance Company expressed concern that the rule restricted the ability of practitioners conducting independent examinations for insurance claims to request examinations. The Department stated that the proposed rule is not intended to preclude radiographic examination by independent medical examiners as long as the

examination is ordered by a licensed practitioner of the healing arts. Proposed rule 4730.1530 is needed and reasonable to ensure that unnecessary x-ray examinations are not given to patients.

Minnesota_Rule_4730.1600_-_Requirements_for_Shielding_in_Installations.

44. Minnesota Rule 4730.1600 was proposed for repeal in this proceeding. At the hearing, the Department withdrew this rule from those being repealed, on the ground that the shielding requirements are still needed to protect persons in facilities operating prior to this rulemaking. Since the proposal relates to an existing rule, the Administrative Law Judge does not have jurisdiction to examine the rule part for need or reasonableness. The Department may withdraw Minnesota Rule 4730.1600 from the repealer. Such withdrawal is not a substantial change.

Proposed_Rule_4730.1620_-_General_Shielding_Requirements_for_Dental Radiographic_Facilities.

45. Following the hearing, the Department reorganized proposed rule 4730.1620 by transferring language from proposed rule 4730.1950. This reorganization puts all of the dental shielding requirements in the same location. Moving the language from one part to another is not a substantial change. The rule, as modified, was not criticized by commentators and is, with one exception, needed and reasonable. Subpart 1(A) requires barriers at any area struck by the useful beam of an x-ray. The item then states: "In many cases structural materials of ordinary walls suffice as a protective barrier without the addition of special shielding material." This sentence contains no standard as to what an "ordinary wall" is, or when such a wall does or does not provide adequate shielding. Applying this rule would be at best problematic, and at worst a violation of due process, since the affected registrant would have no notice of what conduct violates the rule. This constitutes a defect. To cure the defect, the Department must delete that sentence. The Administrative Law Judge recommends that the Department incorporate the information in MDOH Exhibit 48 (NCRP Report No. 35, Dental_X-ray_Protection, Chapter 3, Structural Shielding Design) as a formula which will state a specific standard to replace the defective sentence. Deleting the defective sentence would also cure the defect. If the MDOH wishes to replace that sentence with a standard, it must locate the information supporting that standard in the rulemaking record and reference that information when this rule (together with the rulemaking record) is submitted to the Chief Administrative Law Judge for review. Adding a standard based on NCRP Report No. 35 would not be a substantial change, since the originally proposed language (now subpart 2 of this rule part) incorporated that document.

Proposed_Rule_4730.1630_-_General_Requirements_for_Therapeutic_X-ray

Facilities.

46. Dr. McCullough suggested that the requirements for therapeutic x-ray facilities, allow a closed circuit television system as an alternative to an observation window, rather than as an additional option. The Department agreed with this suggestion and modified proposed rule 4730.1630, subpart 3 accordingly. The proposed rule, as modified, is needed and reasonable to permit alternative viewing systems during radiation therapy. The modification does not constitute a substantial change.

Proposed_Rule_4730.1655_-_Required_Quality_Assurance_Program_Procedures.

47. Under proposed rule 4730.1655, eac

The DVA suggested that, under subpart 3(B), tests should be conducted after any changes to the facility or equipment, not only when a radiation hazard may exist. The MDOH agreed with the suggestion and altered the subpart to require a QA test whenever a change had occurred which caused the equipment to fall below minimum standards. The subpart, as modified, is needed and reasonable. The change does not constitute a substantial change.

Proposed_Rule_4730.1665_-_Computer_Tomography_Quality_Assurance_Measurements.

48. The DVA suggested a change to proposed rule 4730.1665 identical to that accepted by the Department in the preceeding Finding. The MDOH proposes that this rule be changed in the same fashion. The Department noted that by requiring tests whenever a change occured causing the equipment to fall below minimun standards, a contradiction within this rule part is avoided. Proposed rule 4730.1665 is needed and reasonable to protect the persons affected by the use of computer tomography. The modification clarifies the rule, is found to be needed and reasonable, and does not constitute a substantial change.

Proposed_Rule_4730.1670_-_Radiation_Safety_Surveys.

49. As originally proposed, radiation safety surveys were to be conducted on an annual basis under proposed rule 4730.1670. Dr. Bruce Gerbi, University of Minnesota Radiation Therapy Department; the DVA; the MDA; and Dr. McCullough disputed the need for an annual survey. Several of these commentators expressed the opinion that surveys are needed only at the time of initial installation or when there is a change in equipment. The Department reconsidered the rule requirement and agreed with the commentators. The change is consistent with the commentators' suggestion for diagnotic and therapeutic devices under subpart 1. The modification is needed and reasonable to require full analysis of radiation systems when problems are likely to develop. The modification is not a substantial change.

50. Subpart 2 governs monitoring equipment. The MDOH changed the frequency of surveys from annually to biennially. The change to once every two years balances the impact of the survey requirement with the need to ensure the safety of persons in the vicinity of the equipment. Proposed rule 4370.1670 is needed and reasonable, as modified. The change to subpart 2 does not constitute a substantial change. The other changes to proposed rule 4730.1670 eliminate redundant language in subparts 3 and 4, and do not constitute substantial changes.

Proposed_Rule_4730.1675_-_Calibrations.

51. Proposed rule 4730.1675 sets the standards for calibrating diagnostic systems in subpart 1, therapeutic systems of less than one MV (megavoltage photon) in subpart 2, and therapeutic systems of greater than one MV in subpart 3. Subpart 1 requires recalibration when components are changed or replaced and when the system falls below the minimum criteria set forth in the rules. Since the amount of radiation used in diagnostic systems is lower than that in therapeutic systems, the infrequent calibration required under subpart 1 is adequate to protect persons in contact with those systems. Therapeutic systems can deliver larger doses of radiation, and the need for an accurate dosage compels a more frequent calibration schedule for that equipment. Subpart 2 requires calibration of the radiation output every year and a verification of the dosage regulation every two years. Mary Fox suggested that certain other tests be added to the calibration routine. The MDOH agreed with that suggestion and added verification of the applicablity of the inverse square law, skin-to-source distance (SSD) indicators, value of the timer end effects, and the half value layer. These tests will prevent excessive dosages through inaccurate or extended exposure. The additions to subpart 2 are needed and reasonable and do not constitute substantial changes. The Department also changed the designation of megavoltage ph

52. The Department participated in detailed discussions with Dr. McCullough and Mary Fox concerning subpart 3, governing the calibration of therapeutic x-ray systems of greater than one MV. As a result of these discussions, the MDOH made a number of modifications to subpart 3. These changes, and the reasons supporting them, are detailed in the MDOH Response to Comment, at 31-33. The Administrative Law Judge has examined these modifications and finds that they do not constitute substantial changes. The subpart, as modfified, is needed and reasonable.

Proposed_Rule_4730.1680_-_Therapeutic_X-ray_System_Spot_Checks.

53. Due to the importance of accurate calibration in therapeutic x-ray systems, proposed rule 4730.1680 requires spot checks of those systems every six months. Dr. McCullough suggested that this provision should apply to all therapeutic systems. The MDOH agreed with this comment and deleted the

limitation of this part to those systems over 150 kVp. The Department also added references to calibration and beam characteristics to subpart 1. The additional language clarifies the scope of the spot checks. The subpart is needed and reasonable to ensure that therapeutic systems are in safe operating condition between surveys. The changes clarify the subpart and do not constitute substantial changes.

54. Mr. Nelson and Mr. Staiger suggested that the last phrase of subpart 2, item G be deleted to prevent the use of out of calibration equipment when adjusting therapeutic systems. The Department agreed with this comment and deleted that language. The modification ensures a higher degree of accuracy in calibrating equipment and is needed and reasonable. The modification is not a substantial change.

Proposed_Rule_4730.1685_-_Medical_Particle_Accelerator_Quality_Assurance.

55. The Department proposes to change the calibration interval found in subpart 1 of proposed rule 4730.1685 from one year to two years for medical particle accelerator systems. In addition, the Department seeks to delete subpart 2. These modifications will conform this rule part to proposed rule 4730.1670, as modified. The changes were suggested by Dr. McCullough and Dr. Gerbi. Since the changes merely conform this part to other sections of the rules, they are not substantial changes. Requiring calibration of medical particle accelerator systems is needed and reasonable as discussed at Finding 51 above.

Proposed_Rule_4730.1688_-_In-service_Education_in_Quality_Assurance.

56. Every registrant is required to provide training about quality assurance to its employees under proposed rule 4730.1688. The DVA suggested that registrants be required to maintain employee training attendance documentations. The Department accepted that suggestion and added the requirement that employees sign or initial an attendence record to be retained by a registrant for the Department's inspection. Requiring a registrant to provide training and to keep a record of that training is needed and reasonable to achieve compliance with the rules governing the use of ionizing radiation. The modification does not constitute a substantial change.

Proposed_Rule_4730.1690_-_Quality_Assurance_Records.

57. The DVA objected to proposed rule 4730.1690, subpart 1 as being unreasonable because the rule contained no limit on the length of time equipment records must be kept by a registrant. The Department responded by adding language requiring record retention until the next inspection by the Commissioner. No commentator objected to this time period. Minn. Stat. Þ 144.121, subd. 2 mandates an inspection of each radiation source at least once every four years. The requirement in subpart 1 that records must be kept until an inspection is needed and reasonable to carry out the MDOH's statutory

responsibilities. The modification integrates the record retention policy into
the Department's inspection schedule and does not constitute a substantial change.

58.

Proposed_Rule_4730.1691_-_Minimum_Diagnostic_Quality_Assurance_Tests_for_a Quality_Assurance_Program_for_Facilities.
Proposed_Rule_4730.1693_-_Therapy_Quality_Assurance.
Proposed_Rule_4730.1695_-_Quality_Assurance_Criteria_for_External_Beam Teletherapy_and_Simulation_Systems.

59. Proposed rules 4730.1691, 4730.1693, and 4730.1695 set out the tests
which must be performed at differing intervals for x-ray equipment and the acceptable minimums which the equipment must meet to operate safely and efficiently. The MDA and Dr. Terese Tomanek, President of the Minnesota Chiropractic Association, objected to the testing provisions on the ground that
the frequency of the testing is unnecessary. Further, both commentators suggested that the costs of compliance with the testing schedule would be an undue burden on small clinics and solo practitioners. The MDA suggested that the equipment needed to carry out the testing required would cost between $1,500 and $3,000 and this amount is too much for small practices.

The Department cited its experience in inspecting facilities as demonstrating the need for the testing schedules. According to the MDOH, over
50 per cent of mammographic facilities were underdeveloping radiographs. MDOH
Hearing Presentation, at 17. To obtain adequate mammograms in that situation,
the level of radiation exposure is increased. Id. Other examples of improper
use of x-ray equipment resulting from inadequate testing were cited at the hearing. The Department introduced MDOH Exhibit 80 showing that the total cost
of the diagnostic equipment needed for compliance with the proposed testing requirements is approximately $1,000. The Department pointed out that nothing
in the proposed rules prohibits sharing the necessary testing equipment. The MDOH emphasized that the responsibility for safe operation of x-ray facilities
rests with the registrant and the equipment required for these tests is necessary to ensure safe operation of x-ray facilities. The Department has shown that establishing testing schedules is needed. The cost of equipment does not make the proposed rules unreasonable.

The proposed testing schedules are taken from NCRP Report 99 and the American Association of Physicists in Medicine Report 13. These documents are
widely accepted as industry standards for quality assurance testing. For the most part, taking quality assurance standards and frequency of testing from these documents is reasonable. However, the tests in proposed rules 4730.1693,

subparts 4 (items 5 and 6), subpart 6 (item 5) and 4730.1695, subpart 1 (item B
(5) and (6)) and subpart 6 (item A) do not specify the frequency of testing. The Administrative Law Judge recognizes that no frequency is suggested in the supporting documents for these rule parts. Nevertheless, for a test to be required in a rule, the frequency of the testing must be specified or the rule
is unenforceable. Omitting a frequency requirement in the items cited constitutes a defect. The Department may cure the defect either by deleting the test requirements, or by specifying a minimum testing frequency for each test. If the Department chooses to specify a frequency for each test, it must
find facts in the record to support the frequency chosen. If the MDOH wants to
include these tests in the annual test requirement, it may do so. The record in this proceeding is adequate to support an annual testing requirement for these rule parts. Once a frequency is set for the tests, all of the testing under these rule parts will be found to be needed and reasonable to protect the
health of persons exposed to ionizing radiation.

Some of the tests required by the Department do not specify a minimum criterion which must be met. However, this lack of a testing criterion does not constitute a defect. The intent behind the test is to alert the user to characteristics of the particular equipment and to inform the user when that particular equipment is not operating correctly. Failur

60. The MDOH made numerous modifications to the testing provisions in response to comments received in the rulemaking process. Those modifications,
and the reasons supporting them, are set forth in the Department's post-hearing
response. MDOH Response to Comments, at 37-80. All of the changes are based on comments by interested persons and are consistent with prevailing practices
in the use of x-ray facilities in Minnesota. The modifications improve the clarity of the rules and do not constitute substantial changes.

Proposed_Rule_4730.2050_-_Veterinary_Medicine_Radiographic_Installations.

61. The DVA objected to proposed rule 4730.2050, subp. 3(C) as contradictory. The MDOH reviewed the provision and noted that the item appeared to prohibit a person holding an animal to obtain an examination and then set standards to follow when a person holds an animal to obtain an examination. The Department deleted the portion of the rule that appeared to prohibit the practice of holding an animal for examinations. The item, as modified, is needed and reasonable and the change does not constitute a substantial change.

Proposed_Rule_4730.2450_-_X-ray_and_Electron_Therapy_Systems_with_Energies_of of_One_MV_and_Above.

62. Additional standards which must be met by certain systems are set out
in proposed rule 4730.2450. These standards are intended to place tight controls on radiation sources which are powerful enough to deliver very harmful

dosages of radiation during a brief exposure. As with other technical standards in these proposed rules, the MDOH made numerous modifications to this rule part in response to comments received in the rulemaking process. Those modifications and the reasons given for the changes are set forth in the Department's post-hearing response. MDOH Response to Comments, at 47-52. The changes arise from comments made by Dr. McCullough and Mary Fox. These changes alter some of the terminology in the rule part; clarify when manual reset of dose monitoring is required; provide flexibility in the location of emergency "off" switches; require interlocks to exclude inappropriate beam modifiers; and permit a three degree tolerance in the angle of moving beam therapy. Additionally, the MDOH rewrote subpart 18 in response to a comment by Dr. McCullough that the subpart seeks the wrong information. The modifications throughout the proposed rule part clarify the Department's intent. The modifications do not constitute substantial changes. Proposed rule 4730.2450, as modified, is needed and reasonable.

Proposed_Rule_4730.2475_-_Radiation_Safety_Requirements_for_the_Use_of_Medical Particle_Accelerators.

63. Proposed rule part 4730.2475 establishes a number of requirements which medical particle accelerators must meet in addition to the general requirements found in proposed rule part 4730.0100 to 4730.1695. The additional requirements are intended to ensure safe operation of these devices since they are more complicated than diagnostic x-ray machines and the applications for such devices are not standardized (unlike diagnostic imaging). Subpart 2 requires appointment of a medical committee to oversee the innovative use of medical particle accelerators. The Department modified this part at the urging of Dr. McCullough to clarify that the committee is needed for research purposes, not for diagnosis or therapy applications. Mary Fox suggested that the rule should require that a therapeutic radiological physicist be on the medical committee. The Department agreed that the committee needs a person with that expertise and modified subpart 2 accordingly. Subpart 2, as modified, is needed and reasonable to ensure the safe operation of medical particle accelerators. The modifications do not constitute substantial changes.

64. The Department altered subpart 3 to make the "off" switch provision consistent with other rule parts, discussed at Finding 62 above. The modification standardizes similar parts of the pr

65. Subpart 5(B) requires that all interlocks on medical particle accelerators be checked on a monthly basis. Dr. Gerbi suggested that doing so was unneccesary and possibly harmful to safe operation of these devices. The MDOH declined to adopt his suggestion that only key interlocks be checked. Failure of an interlock can cause death or serious harm through the uncontrolled exposure of a person to radiation. The Department has shown that

checking all interlocks is a needed and reasonable requirement. The Administrative Law Judge suggests that any registrant with a medical particle accelerator which will be harmed by monthly checks of all interlocks consider requesting a variance under proposed rule 4730.1475. A variance from the Department can exempt the registrant from strict compliance with the interlock
requirement while assuring the MDOH that safety will not be compromised.

66. Subpart 5(D) relating to the disconnection of interlocks, was criticized by commentators as being unduly restrictive. They pointed out that
interlocks are frequently disconnected during servicing and should not require
the safeguards required in this rule part. The Department agreed with the comments and modified the item to apply only when interlocks are disconnected for patient treatment. A suggestion by Dr. McCullough that the radiation safety officer be permitted to delegate authority to disconnect interlocks was
also incorporated into the item by the Department. The changes clarify the intent of the rule and ease compliance by registrants by allowing some flexibility in using medical particle accelerators. Subpart 5 is needed and reasonable. The modifications do not constitute substantial changes.

Compliance_Manuals_for_Particular_Professions.

67. The MDA objected strenuously to the format of the proposed rules. The manner in which the rules are organized requires the reader to examine the
entire rule chapter to locate the specific standards which apply to a particular health professional. This is particularly problematic for health professionals, who are not experts in radiology, but use x-ray equipment as an
adjunct to their practices. Professionals such as dentists and chiropractors oftentimes are not knowledgable about the technical aspects of radiology equipment or the standards the equipment must meet. The MDA asserted the the Department must remedy this problem by publishing a "compliance manual" tailored to the needs of particular professionals. Failing to publish this manual would, according to the MDA, render the proposed rules unreasonable. Further, the MDA asserted that the MDOH has the statutory obligation to publish
this manual under Minn. Stat. Þ 144.05(d).

Under Minn. Stat. Þ 144.05(d), the Commissioner of MDOH has the authority
to "affect the quality of public health and general health care services by providing consultation and technical training for health professionals and paraprofessionals." As a part of this rulemaking proceeding, the Department has offered to:

a) work with the Office of the Revisor to prepare an index to the proposed rules;
b) work with the Office of the Revisor to develop extracts of the proposed rules containing all the requirements applicable to individual professions; and,
c) rewrite the rules, as needed, in future rulemaking proceedings.

MDOH Response to Comments, at 54.

The Department has followed the Revisor's drafting recommendations in writing these proposed rules. The Revisor strongly discourages repetition of rules where cross-referencing will attain the same result. The Department has taken great pains to render each rule part understandable by those persons who must comply with the rules. If the Department were to prepare a "compliance manual" as requested by the MDA, its work product could constitute improper rulemaking if the manual differed significantly from the promulgated rules. It would be more appropriate

Standards_for_Operators_and_Quality_Assurance_Personnel.

68. The MDA asserted that the proposed rules on quality assurance testing are unreasonable, since the Department has not shown that adequate numbers of qualified persons are available to conduct the testing within the time constraints mandated by the proposed rules. To show that a rule is reasonable, the Department need only show that the rule is rationally related to the end to be achieved. Mammenga_v._Department_of_Human_Services, 442 N.W.2d 786, 789-90 (Minn. 1989). Whether a particular individual will be able to find a person qualified to perform that testing is not a ground to find the rule unreasonable (just as Mammenga could not show the Department of Human Services rule was unreasonable despite the impossiblity of her meeting the eligibility requirement for general assistance benefits because her county of residence did not offer enough credits). The MDOH has shown that testing on a regular basis is rationally related to eliminating undue exposure to ionizing radiation. That showing by the MDOH is all that is required to establish that the testing requirements are reasonable.

Many commentators suggested that these rules should require the licensing of operators and QA personnel, and set forth the qualifications for licensure. The MDOH is constrained by the requirements of Minn. Stat. Chapter 214, which establishes a process for the Department to regulate health related professions. The Department cannot avoid this statutory requirement by incorporating qualifications for operators or QA personnel in these rules. Rather, the Department will have to act on a case-by-case basis to determine whether specific individuals are qualified to conduct QA tests or operate x-ray equipment. While this method is not efficient, it is not inconsistent with statutory authority. The Department may wish to seek legislation for specific statutory authority to license operators and QA professionals.

Based upon the foregoing Findings of Fact, the Administrative Law Judge makes the following:

CONCLUSIONS

1. The Minnesota Department of Health (MDOH) gave proper notice of this rulemaking hearing.

2. The MDOH has substantially fulfilled the procedural requirements of Minn. Stat. ÞÞ 14.14, subds. 1, 1a and 14.14, subd. 2, and all other procedural requirements of law or rule so as to allow it to adopt the proposed rules.

3. The MDOH has demonstrated its statutory authority to adopt the proposed rules, and has fulfilled all other substantive requirements of law or rule within the meaning of Minn. Stat. ÞÞ 14.05, subd. 1, 14.15, subd. 3 and 14.50 (i) and (ii), except as noted at Findings 45 and 59.

4. The MDOH has demonstrated the need for and reasonableness of the proposed rules by an affirmative presentation of facts in the record within the meaning of Minn. Stat. ÞÞ 14.14, subd. 2 and 14.50 (iii).

5. The additions and amendments to the proposed rules which were suggested by the MDOH after publication of the proposed rules in the State Register do not result in rules which are substantially different from the proposed rules as published in the State Register within the meaning of Minn. Stat. Þ 14.15, subd. 3, and Minn. Rule 1400.1000, subp. 1 and 1400.1100.

6. The Administrative Law Judge has suggested language to correct the defects cited in Conclusion 3, as noted at Findings 45 and 59.

7. Due to Conclusions 3 and 6, this Report has been referred to the Chief Administrative Law Judge for his approval pursuant to Minn. Stat. Þ«14.15, subd. 3.

8. Any Findings which might properly be termed Conclusions and any Conclusions which might properly be termed Findings are hereby adopted as such.

9. A Finding or Conclusion of need and reasonableness in regard to any particular rule subsection does not preclude and should not discourage the MDOH from further modification of the proposed rules based of the public comments, provided that no substantial change is made from the proposed rules as originally published, and provided that the rule finally adopted is based upon facts appearing in this rule hearing record.

Based upon the foregoing Conclusions, the Administrative Law Judge makes the following:

RECOMMENDATION

IT IS HEREBY RECOMMENDED that the proposed rules be adopted except where otherwise noted above.

Dated this 21st_ day of June, 1991.

Phyllis_A._Reha_____

PHYLLIS A. REHA
Administrative Law Judge

Reported: Tape Recorded; No Transcript.